Filing Date: May 9, 2006

Amendments to the claims:

This listing of claims will replace all prior versions, and listing, of claims in the

application:

Listing of Claims:

Claims 1-87 (Cancelled).

88. (Previously presented): A topotecan monohydrochloride pentahydrate product

having an X-ray powder diffraction pattern that is substantially the same as Figure 1.

89. (Previously presented): A topotecan monohydrochloride pentahydrate product

having an inverse second derivative FT-IR spectrum for the spectral region of 1800 cm⁻¹-

1500 cm⁻¹ that is substantially the same as Figure 3.

90. (Previously presented): The product according to claim 88, wherein the product

has a water content range between from about $\geq 10\%$ w/w% to about ≤ 17 w/w%.

91. (Previously presented): The product according to claim 88, wherein the product

has a water content in a range of about 10.5 wt% to about 16.5 wt%.

92. (Previously presented): The topotetcan monohydrochloride pentahydrate product

having an X-ray diffraction pattern that is substantially the same as Figure 1,

wherein the product is prepared by a process comprising the steps of:

[a] forming an aqueous organic solvent mixture containing topotecan

monohydrochloride, wherein the organic solvent of the aqueous organic solvent mixture is

selected from the group consisting of acetone and tetrahydrofuran, and wherein the ratio of

organic solvent to aqueous solvent in the aqueous organic solvent mixture is from about 1.5:1

to about 3:1;

[b] recrystallizing the topotecan monohydrochloride from the aqueous organic solvent

mixture to precipitate the topotecan monohydrochloride pentahydrate product; and

[c] collecting, by filtration, the topotecan monohydrochloride pentahydrate product.

3

Filing Date: May 9, 2006

93. (Previously presented): The product according to claim 92, wherein the aqueous organic solvent mixture comprises an aqueous mineral acid solution.

- 94. (Previously presented): The product according to claim 92, wherein the aqueous mineral acid solution is a 0.05 N aqueous hydrochloric acid solution.
- 95. (Previously presented): The product according to claim 92, wherein the aqueous organic solvent mixture comprises a mixture of acetone and a 0.05 N aqueous hydrochloric acid solution.
- 96. (Previously presented): The product according to claim 92, wherein process step [b] comprises recrystallizing the topotecan monohydrochloride from the aqueous organic solvent mixture which comprises acetone and 0.05 N aqueous hydrochloric acid, wherein the v/v ratio of acetone to aqueous hydrochloric acid is about 2:1.
- 97. (Previously presented): The product according to claim 92, prepared by a process further comprising the steps of:
- first dissolving topotecan monohydrochloride in a heated aqueous organic solvent solution mixture;
- crystallizing or recrystallizing the topotecan monohydrochloride pentahydrate from the heated solution by cooling the solution; and
- filtering the resulting recrystallized topotecan monohydrochloride pentahydrate product and drying.
- 98. (Previously presented): The product according to claim 97, wherein the heated aqueous organic solvent solution mixture is a mixture of acetone and 0.05 N aqueous hydrochloric acid heated to a temperature of about 58°C and the v/v ratio of acetone to aqueous hydrochloric acid is about 2:1.
- 99. (Previously presented): The product according to claim 97, wherein the heated solution is cooled at a rate of about 0.1°C/min to about 1°C/min.

Filing Date: May 9, 2006

100. (Previously presented): The product according to claim 97, wherein the heated solution is cooled at a rate of about 0.25°C/min.

- 101. (Previously presented): The product according to claim 97, wherein, in the crystallization or recrystallization process, the solution is cooled to a temperature of about room temperature to about 0°C.
- 102. (Previously presented): A topotecan monohydrochloride pentahydrate product having an X-ray diffraction pattern that is substantially the same as Figure 1, wherein the product is prepared by a process comprising the steps of:
- [a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the aqueous solvent of the aqueous organic solvent mixture is an aqueous mineral acid solution, the organic solvent of the aqueous organic solvent mixture is selected from the group consisting of acetone and tetrahydrofuran, and wherein the v/v ratio of organic solvent to aqueous solvent is about 8:1;
- [b] slurrying the topotecan monohydrochloride with the aqueous organic solvent mixture to form the topotecan monohydrochloride pentahydrate product; and
 - [c] collecting, by filtration, the topotecan monohydrochloride pentahydrate product.
- 103. (Previously presented): The product according to claim 102, wherein the aqueous organic solvent mixture comprises a 0.05 N aqueous hydrochloric acid solution.

Claims 104-105 (Cancelled).

- 106. (Previously presented): A process for preparing the product according to claim 88 comprising the steps of:
- [a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the organic solvent of the aqueous organic solvent mixture is selected from the group consisting of acetone and tetrahydrofuran;
- [b] recrystallizing the topotecan monohydrochloride from the aqueous organic solvent mixture to precipitate the topotecan monohydrochloride pentahydrate product; and
 - [c] collecting, by filtration, the topotecan monohydrochloride pentahydrate product.

Filing Date: May 9, 2006

107. (Previously presented): The process according to claim 106, wherein the aqueous organic solvent mixture comprises an aqueous mineral acid solution.

- 108. (Previously presented): The process according to claim 107, wherein the aqueous mineral acid solution is a 0.05 N aqueous hydrochloric acid solution.
- 109. (Previously presented): The process according to claim 106, wherein the aqueous organic solvent mixture comprises a mixture of acetone and a 0.05 N aqueous hydrochloric acid solution.
- 110. (Previously presented): The process according to claim 106, wherein step [b] comprises recrystallizing the topotecan monohydrochloride from the aqueous organic solvent mixture which comprises acetone and 0.05 N aqueous hydrochloric acid, wherein the v/v ratio of acetone to aqueous hydrochloric acid is about 2:1.
- 111. (Previously presented): The process according to claim 106, further comprising:
- first dissolving topotecan monohydrochloride in a heated aqueous organic solvent solution mixture;
- crystallizing or recrystallizing the topotecan monohydrochloride pentahydrate from the heated solution by cooling the solution; and
- filtering the resulting recrystallized topotecan monohydrochloride pentahydrate product and drying.
- 112. (Previously presented): The process according to claim 111, wherein the heated aqueous organic solvent solution mixture is a mixture of acetone and 0.05 N aqueous hydrochloric acid heated to a temperature of about 58°C and the v/v ratio of acetone to aqueous hydrochloric acid is about 2:1.
- 113. (Previously presented): The process according to claim 111, wherein the cooling rate is in the range of about 0.1°C/min to about 1°C/min.

Filing Date: May 9, 2006

114. (Previously presented): The process according to claim 111, wherein, in the crystallization or recrystallization process, the solution is cooled to a temperature of about room temperature to about 0°C.

- 115. (Previously presented): A process for preparing the product according to claim 88 comprising the steps of:
- [a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the aqueous solvent of the aqueous organic solvent mixture is an aqueous mineral acid solution, the organic solvent of the aqueous organic solvent mixture is selected from the group consisting of acetone and tetrahydrofuran, and wherein the v/v ratio of organic solvent to aqueous solvent is about 8:1
- [b] slurrying the topotecan monohydrochloride with the aqueous organic solvent mixture to form the topotecan monohydrochloride pentahydrate product; and
 - [c] collecting, by filtration, the topotecan monohydrochloride pentahydrate product.
- 116. (Previously presented): The process according to claim 115, wherein the aqueous organic solvent mixture comprises a mixture of acetone and a 0.05 N aqueous hydrochloric acid solution.